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Suture-TOOL: A suturing device for swift and standardized abdominal aponeurosis closure

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ABSTRACT

Introduction: Surgeons can reduce incisional hernia formation by adhering to standardized techniques for incisional wound closure. This is often neglected by the time a long operation is to be ended and can lead to the risk of developing an incisional hernia or a wound rupture. To address this issue, a suturing machine (Suture-TOOL) was developed for swift and standardized abdominal closure. The aim was to compare the user safety, speed, and suturing quality between Suture-TOOL and manual Needle-Driver suturing.

Method: Fifteen surgeons who were specialists in surgery, urology, and gynaecology as well as surgical trainees were invited. The Suture-TOOL was presented to the surgeons who read the instructions for use before starting the test. Each surgeon closed nine 15 cm-long incisions in a human body model; six with Suture-TOOL and three with the Needle-Driver technique. Gloves were examined for puncture damage. Endpoints were suture-length/wound-length (SL/WL)-ratio, closure time, number of stitches, learning curve, and glove puncture rate. A VAS-evaluation concerning different Suture-Tool user impressions was completed.

Results: A SL/WL-ratio $\geq$4 was 98% for Suture-TOOL versus 69% for Needle-Driver ($p < 0.001$). Suture time was shorter for Suture-TOOL ($p < 0.001$). Wound stitch count was higher for Needle-Driver ($p = 0.013$). The median SL/WL-ratio was similar between groups. The learning curve plateaued after three closures using Suture-TOOL. Two glove punctures were detected—all in the Needle-Driver group. Suture-TOOL received high VAS scores for all measured functionalities.

Conclusion: Suture-TOOL is a promising device for clinical use. It is safe, easy, and fast resulting in a high-quality suture lines with a short learning curve and a high functionality ranking.

Introduction

Incisional hernia imposes a large socio-economic burden worldwide. It is a common complication to abdominal surgery and affects up to 35% of the patients [1]. Some patients with incisional hernia are reluctant or unfit to undergo further surgery. To live with an incisional hernia has a significant impact on health-related quality of life (QoL) and body image [2,3]. Incisional hernia formation after primary midline incisional closure is reported to be 17% after three years [4]. Many factors for incisional hernia are patient-dependent including age, BMI, and sex [5].

Two important factors are the precise primary midline incision and the closure technique. To reduce incisional hernia development, it is recommended that the suture-length to wound-length ratio (SL/WL) be $\geq$4. The ratio should be acquired with small bites placed tightly (5 mm bites 5 mm apart) [6–8]. The rationale for small bites is to include only the aponeurosis in the suture line—this has been experimentally shown to give less wound edge separation compared to large bites [9]. Small bites also give a higher tensile strength [10]. The technique of achieving SL/WL of $\geq$4 with small bites is roughly 30% more time-consuming than using larger bites [6,7].

Although there are scientific evidence and guidelines to support the use of small bites and the SL/WL of $\geq$4, the adherence is rare; there is a large amount of individual variation among surgeons [11,12]. Thus, there is a need for an incision closure method that is safe, easy to learn, available to many users, and suitable for different clinical settings. Ideally, the method should work in the hands of different users and be reproducible. The method should also be fast.

A suturing device for swift and standardized abdominal closure (Suture-TOOL) was developed to align the differences in an interpersonal performance [13]. The device has been further developed and

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re-designed with input from several potential users including different surgeons and scrub nurses. Re-design included adaptation for manufacturing in plastic materials, slimmer tip, lower device weight and a needle construction with less friction. The aim was to compare Suture-TOOL to manual Needle-Driver suturing concerning adherence to SL/WL ratio ≥4, incisional closure time, and glove punctures in a realistic test bed consisting of a human body model.

Methods

This is an experimental study comparing Suture-TOOL and Needle-Driver suturing in a human model. The study was performed at the Autopsy Unit at the Department of Pathology, Skåne University Hospital, Lund, Sweden. A midline incisional closure model was prepared using adult humans selected for autopsy. Ethical approval was obtained from the Swedish Ethical Review Authority (2019-04626). Bodies of both sexes without a previous midline incision and who tested negative for Covid-19 were included. The primary endpoint was adherence of SL/WL-ratio ≥4. Secondary endpoints were introduction time, incisional closure time, Suture-TOOL learning curve, and glove puncture rate.

Suture-TOOL

Suture-TOOL was developed by a surgeon (author 1) in collaboration with a medical technology development team associated with Lund University. It is an automatic hand-held hand-powered suture device, which uses a double-ended needle with a centrally attached polydioxanone (PDO) thread (Fig. 1) [13]. The purpose of Suture-TOOL was to facilitate a speedy, safe, and standardized suture line for aponeurosis adaptation.

Suture techniques

The aim was to achieve a SL/WL-ratio ≥4. A 90-cm-long thread was used for both techniques. The Suture-TOOL and Needle-Driver techniques for incision closures are described in Fig. 2. To facilitate the use of small bites in the Needle-Driver group the CT-2 needle on a 2-0 Monocryl® (Ethicon, Somerville, NJ, USA) suture was used.

Study model

A separate autopsy room was used. Bodies were put on the autopsy table and draped with surgical sheaths. Body weight and subcutaneous fat layer thickness was recorded. A 20-cm midline incision was made through the skin and subcutaneous tissue. *Linea alba* was dissected free from subcutaneous fat exposing 2 cm of the rectus fascia. A 15-cm midline incision was carefully made to avoid entering the rectus muscle compartments. Abdominal content was protected using a cloth. Time for preparation of the midline, undermining the subcutaneous fat, was not included in the suturing time.

The study team consisted of a surgeon, an assistant, and an observing research nurse. The surgeon was positioned on the left side and the assistant on the opposite. The observer was positioned cranially to the body. Suturing was performed in a caudal-to-cranial direction.

Test surgeons

Specialists in surgery, gynaecology, urology, and surgical trainees were invited according to availability. The participants had not been exposed to the Suture-TOOL before. Age, sex, surgical specialty, years in surgical practice, dexterity, and glove size were recorded.

Study design

The study design was introduced to the surgeons via email which included pictures and written instructions on how to perform the suture line according to SL/WL-ratio ≥4 with small bites. At the autopsy unit, the test surgeons were introduced to the Suture-TOOL by holding the device while reading the Instructions for Use (IFU). Three Suture-TOOL handling features (device check, needle loading, and forceps operating area) were highlighted and pointed out by the observing research nurse educated in the study design including suture techniques. All further questions were addressed to the IFU. Introduction was finished when the surgeon felt confident in using Suture-TOOL according to IFU. The introduction time was recorded.

The first three runs with Suture-Tool were regarded as practice incisional closures (runs). Each surgeon performed six runs within the test: three with Suture-TOOL and three with Needle-Driver alternating between the techniques. Runs were performed without a start and stop knot. The thread was secured with a clamp. Suture time was defined as the time from the first stitch passing through the aponeurosis until the final stitch. The remaining thread length and number of stitches were recorded and blinded to the surgeon.

Biogel® Eclipse gloves (Mölnlycke Health Care, Göteborg, Sweden) were used. Surgeons with latex allergy added a latex free glove liner. For the six test closures, surgeons shifted gloves after each run, and the gloves were collected in pre-marked Ziplock bags.

After the test session, the surgeon completed a visual analogue scale (VAS) based evaluation survey with eleven statements on Suture-TOOL impressions (Fig. 3). Each statement was scored on a continuous 100-

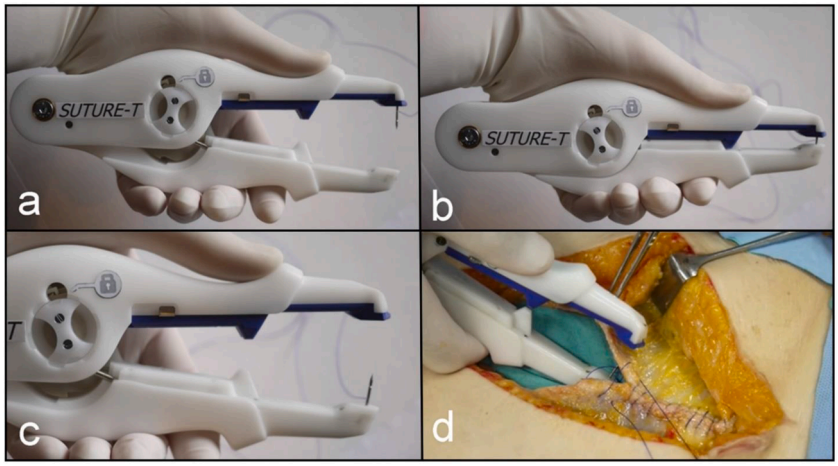

Fig. 1. Suture-TOOL handling a. Needle in upper jaw b. Compressed to transfer the needle to the lower jaw c. Opened and needle is positioned in the lower jaw d. Positioned to close a midline incision.

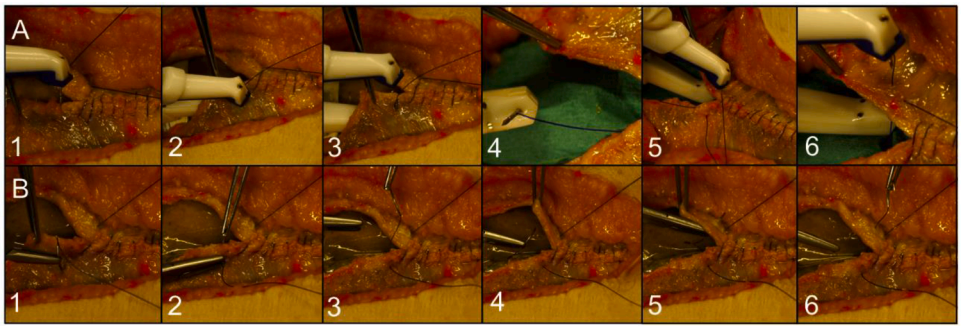

Fig. 2. A. Suture-TOOL suturing sequence 1. Contralateral aponeurosis grasped by forceps and Suture-TOOL positioned for an overstitch 2. Compressed and needle passed through the tissue 3. Needle is transferred to the lower jaw 4. Ipsi-lateral aponeurosis is grasped by the forceps and Suture-TOOL is repositioned 5. Suture-TOOL compressed 6. Needle passed through the tissue and transferred to the upper jaw and one complete stitch is performed B. Manual Needle-Driver (Mayo-Hegar 16 cm, Stille AB, Sweden) suturing sequence. 1. Contralateral aponeurosis grasped by forceps 2. Semi-curved needle is passed through the tissue 3. The needle is grasped by forceps 4. The needle is grasped by the needle driver 5. The needle is passed through ipsi-lateral aponeurosis 6. The needle is grasped by forceps and one complete stitch is performed.

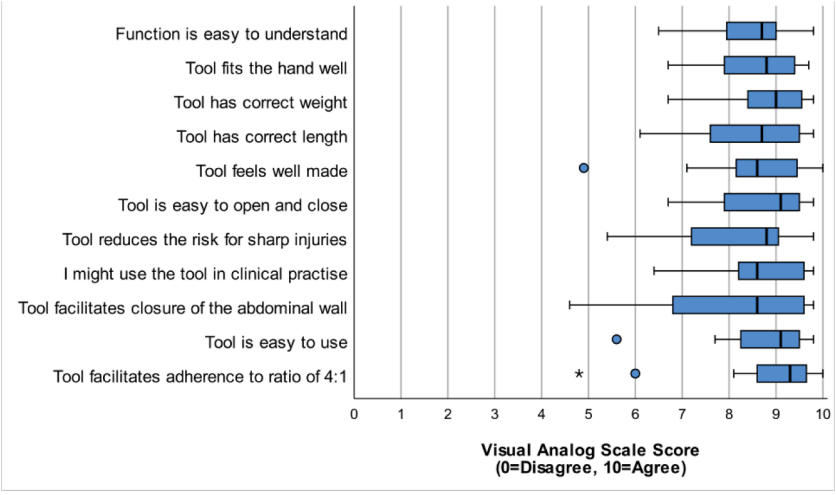

Fig. 3. Figure presents 11 Suture-TOOL statements from a total of 15 users on a VAS scale. Median VAS scores with interquartile range and outliers for different Suture-TOOL functions and usability. Outliers are marked plotted as a small ring and extreme outliers as a star.

mm VAS scale.

Glove integrity test

Glove integrity was tested using the standard "Medical gloves for single use – Part 1: Requirements and testing for freedom from holes (SS-EN- 455-1-2000)". A vertically positioned filling tube holding more than 1000 ml of water was positioned in a test tube holder. The glove was attached to the lower opening of the tube and filled with 1000 ml of blue dyed water. If no leak was detected after two minutes, then the glove was determined to be intact.

Statistical analysis

This analysis used IBM SPSS Statistics for Windows, Version 26 (Armonk, NY, USA). All study measurements were reported as either means with standard deviation (SD) or median (range).

Power calculations for the primary endpoint and adherence to SL/WL ratio $\geq$4 was based on results from two studies [13,14] that showed that the proportion of adherence to SL/WL $\geq$4 was 0.95 for Suture-TOOL suturing and 0.7 for Needle-Driver. To detect a 5% difference with 80% power, 43 closures would be needed for each suturing technique, and thus 15 surgeons (3 closures/technique/surgeon) were required.

Continuous variables were compared using Student t-test and categorical variables using Fishers Chi^2-test. All tests were two-sided, and $p<0.05$ was considered significant.

Results

Fourteen bodies (five females and nine males) were used in the study. The mean body weight was 81 (SD 23.6) kg, and the mean subcutaneous fat layer thickness was 2.4 (SD 0.7) cm. A total of 15 surgeons participated: seven general surgeons, two gynaecologists, one urologist, and five surgical trainees. Four were female. Mean age was 38 (SD 7.9), mean years in surgical practice was 8.8 (SD 6.7), and median glove size was 7.5 (6–7.5).

Suturing and glove tests

The mean theoretical introduction time of Suture-TOOL was 13:00 minutes (SD 5.2). After three runs, the suture time for Suture-TOOL plateaued for all users (learning curve; Fig. 4). Mean suturing time for Suture-TOOL was 4:46 (minutes: seconds; SD 0:54) and for Needle-Driver was 7:05 (minutes: seconds; SD 1:59) ($p<0.001$). The SL/WL ratio $\geq$4 was reached in 44/45 (98%) with Suture-Tool and 31/45 (69%) with Needle-Driver ($p<0.001$). Mean stitch count was 30.0 for Suture-TOOL and 33.7 for Needle-Driver suturing ($p<0.013$). The suture time and achieved SL/WL ratio in the test runs are displayed in Fig. 5. There were 180 gloves tested for leakage. Two leaks were detected—both in the Needle-Driver group ($p=0.497$).

Evaluation of Suture-TOOL

All surgeons completed the survey. All statements received a median

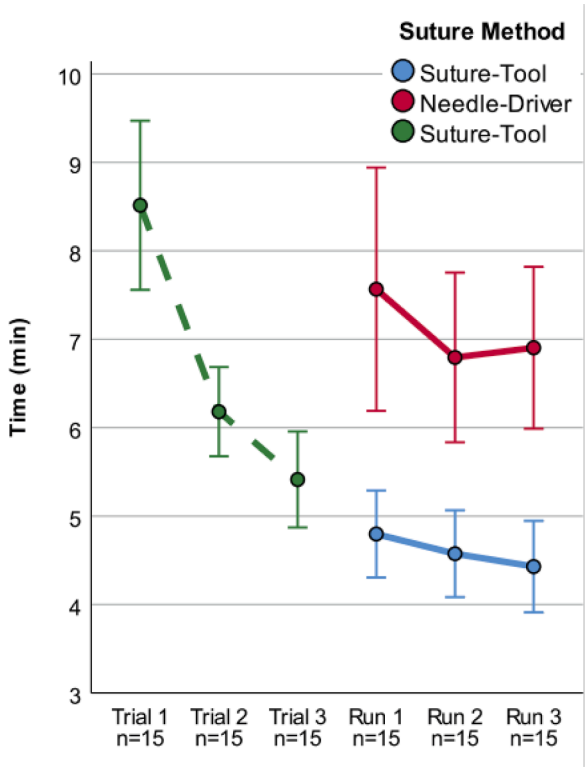

Fig. 4. Learning curve for 15 surgeons performing three runs each with Needle-Driver and six runs with Suture-TOOL suturing. Mean suture time is displayed with 95% confidence interval.

VAS >8.6. The highest scores were given to "Tool facilitates adherence to ratio of 4:1" VAS 9.3 [6–10]; "Tool is easy to open and close" VAS 9.1 (6.8–9.8); "Tool is easy to use" VAS 9.1 (5.6–9.8); and "Tool has the correct weight" VAS 9.0 (6.1–9.8) (Fig. 3).

Discussion

Surgeon vigilance and attention to detail during the intraabdominal part of a surgical procedure can be difficult to maintain after long and strenuous surgeries. The lack of focus can affect the surgeon's ability to uphold the surgical technique for abdominal wall closure required to prevent wound complications. If the task of closing the abdomen could be facilitated by a device for swift and standardized high-quality closure of the abdomen, then it would be a valuable solution to an often neglected challenge. Here, the Suture-TOOL suturing device is evaluated in terms of those requirements.

The study assesses the new generation of Suture-TOOL in a human body model with skin, subcutanesous fat, aponeurosis, bowel content and body fluids. This was important for several reasons: we needed to evaluate the device in a realistic test bed with different users caracteristics, we needed to evaluate the device for unexpected adverse events and mechanical/design issues and we wanted more user input for further development of design and user manual.

Surgeons' adherence to wound closure recommendations is an influential factor for incisional hernia formation. Assessment of surgeons' attitudes reveal several reasons for avoiding guideline recommendations: "Not familiar enough with methods to correctly execute", "Time consuming", "Not reimbursed", and "Concerns about closure-related complications" [11]. A recent Dutch study stated that only 35% of surgeons pursue a SL/WL-ratio ≥4 [12]. This study also showed that trainees in surgery and trauma, vascular, and paediatric surgeries were less likely to achieve a SL/WL ratio ≥4 compared to gastrointestinal and oncologic surgeons. This should increase surgeons' awareness of the abdominal wall closure quality.

Several risk factors for wound complications have been described including obesity and smoking [15,16]. Patients undergoing surgery for colorectal cancer and aortic aneurysm have an increased risk for incisional hernia development [17,18]. Another subgroup with increased risk is patients undergoing laparotomy due to combat trauma [19]. The surgeon performing the procedure is also a risk factor [20]. Williams et al. published a study of 100 consecutive open abdominal surgeries and found that adherence to the SL/WL-ratio ≥4 was lower if the residents closed the abdomen without the supervision of a senior surgeon [14].

Adherence to a SL/WL-ratio ≥4 was 98% for all surgeons using Suture-TOOL. The confidence interval for Suture-TOOL was smaller for both suture time and SL/WL-ratio compared to Needle-Driver suturing. There is a suspicion that exposure of rectus muscles by a non-precise midline incision (surfing) when entering the abdominal cavity is a risk factor for incisional hernia formation. The Suture-TOOL method involves a distinct entrance through the *linea alba* to avoid "surfing". Linea alba was dissected free from subcutaneous fat exposing 3 cm of the rectus fascia, Fig. 1d. In the clinical setting we anticipate that an undermining of 1 cm will be sufficient to accommodate Suture-TOOL and to facilitate a precise incision. The possible relationship between "surfing" and incisional hernia formation should be addressed in another setting.

Suture-TOOL suturing time was 31% shorter compared to Needle-Driver suturing. This represents a reduction in operative time of seven minutes if extrapolated to data on suturing times in a clinical setting [6]. Reducing the operating room time is important for several reasons: It is associated with postoperative complications [21,22] and surgical

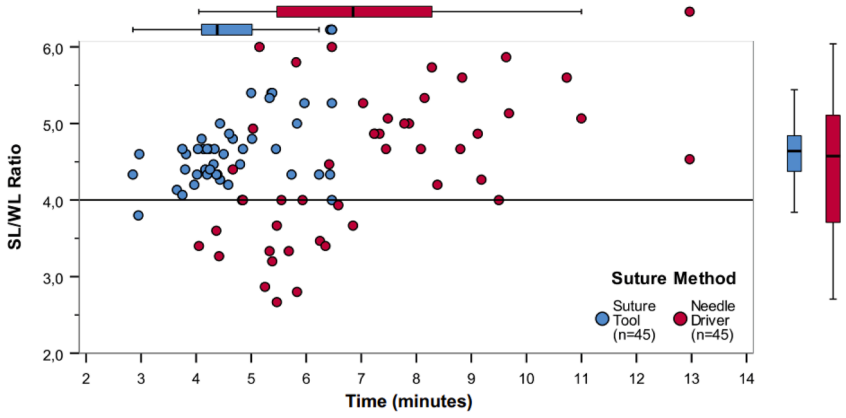

Fig. 5. Incision closures performed in a human body model plotted for Suture Length/Wound Length (SL/WL) ratio in relation to suture time. In the margins Tukey's boxplots show median and interquartile range. 1

resources needs to be optimally utilized. Every minute spent in the operating room is cost driving.

In a recent experimental study by Conway, surgeons estimation on 5mm and 10mm spacing was investigated [23]. The range of estimates for a 5mm distance estimation task was 2.01 to 11.69mm, and for a 10mm task, the range was 4.82 to 19.19mm reflecting that space estimation is difficult. Suture-TOOL has a guide for correct stitch placement. In the present study surgeons were instructed to achieve SL/WL-ratio ≥4 by putting stitches 5mm from the incision and 5mm apart. Correct stitch placement in the model would yield 30 stitches in the 15cm long incision. Mean stitch count was 30.0 for Suture-TOOL and 33.7 for Needle-Driver suturing suggesting that Suture-TOOL facilitates correct stitch placement.

Sharp injury protection in surgery is important to minimize transferring of blood-borne diseases [24]. It has been shown that half of the intraoperative sharp injuries are caused by suture needles and a majority of incidents are with junior surgeons [25,26]. In a Danish questionnaire study, the most common causes for intraoperative sharp injuries were inattentiveness, use of fingers instead of instruments, poor space, and injury inflicted by a colleague [27]. An important feature of the Suture-TOOL is that it keeps the user's hands away from the needle. Two glove punctures were detected—both in the Needle-Driver group. The overall low puncture rate might have been influenced by surgeons being focused on the single task of incision closure but the study was not designed to show a difference in glove puncture rate but was reported according to study protocol.

There is a difference in suture thread handling between Suture-TOOL suturing and Needle-Driver suturing: Suture-TOOL suturing method produce less twisting of the suture and no risk for the needle driver to interfere with the suture thread. This might avoid damaging the suture thread and reduce the risk for suture breakages and subsequent wound rupture which could be an important benefit of the Suture-TOOL device. A suture burst strength comparison study is considered to be included in a future model study.

There are several devices for closure of trocar sites after laparoscopic surgery, e.g., VersaOne™ Fascial Closure System (Medtronic, Minneapolis, USA), Lapro-Shark™ Laparoscopic Fascial Port Closure Device (Brainchild Surgical Device, New York, United States), and LaproClose Trocar Site Closure (LaproSurge Ltd., Watford, UK). These devices place only a few fascial stitches. There is also a sewing machine for laparoscopic surgery, Endo Stitch™ Suture Device (Medtronic, Minneapolis, USA), that facilitates intraabdominal stitching typically while performing fundoplication. However, none of these devices addresses closing the abdomen after open surgery, and, to the best of our knowledge, there is no commercially available device for this task.

The surgeon survey included statements on Suture-TOOL performance and design. All statements received a high median VAS (>8.6) implicating a high user satisfaction with Suture-TOOL. Surgeons ranked "Tool is easy to use", "Tool facilitates a SL/WL-ratio ≥4", and "Tool is easy to open and close" with the highest VAS. These properties are important to achieve an optimal abdominal closure for the patient. However, two users did not agree to the same extent. Both had the smallest glove size, which could have interfered with device handling. However, their technical performance was comparable to the other test surgeons. Surgeons' evaluation is important for ergonomic developments. In general, surgeons prefer instruments that are hassle-free, safe, fast, and easy to learn. The questionaire was developed by the authors for the first study on Suture-TOOL. In hindsite a more neutral language would have been preferable as some statements may be considered leading.

Andrew de Beaux emphasized that closing the abdomen after surgery is a crucial and integrated part of the surgical procedure that needs to be done with meticulous technique via an experienced surgeon to avoid complications. He stated that "closing time is not coffee time" [28].

Our study indicates that closing the abdomen after open surgery with Suture-TOOL is fast, easy to learn, and reproducible.

Conclusion

Suture-TOOL is a promising device for standardized abdominal wall closure. Studies in a clinical setting are forthcoming to further assess device handling, postoperative complications such as wound infections, burst abdomen, and incisional hernia development.

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Disclosures

Monocryl sutures were provided by Ethicon.

GB is founder of Suturion AB. The authors declare that they have no other known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The category in which the manuscript is being submitted

Original research article

Contributing

GB, AM and ME set up the study design. GB collected the data. Statistical analysis performed by GB and PR. All authors collaborated in interpreting the data and writing the manuscript.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

GB are founder of Suturion AB that developed the Sutre-TOOL device.

ME, PR and AM have no conflict of interest

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